

## **REMARKS/ARGUMENTS**

### **I. Status of the Claims**

Claims 1-22, 35, 37-39, 64 and 66-85 are pending. Claims 16 and 18-22 have been withdrawn from consideration by the Examiner as being directed to non-elected subject matter.

Claim 64 has been cancelled without prejudice or disclaimer.

No claims have been added.

Claim 67 has been amended to depend from claim 1. The scope of claim 67 is unchanged.

By this Amendment, no new matter has been added to the application.

### **II. Response to Rejections**

The rejections set out in the Office Action are summarized and addressed as follows.

*(i) Obviousness-type double patenting.* Claims 1-22, 25, 26, 28, 35, 37-39, 64 and 66-85 are provisionally rejected over claims 36-96 of co-pending application no. 10/719,553 ("the '553 application"). The '553 application has not issued as a patent. Accordingly, it is requested that the instant rejection be held in abeyance.

*(ii) Rejection Under 35 U.S.C. §112, second paragraph.* Claim 67 has been rejected as indefinite for failing to narrow its base claim, claim 2. In response, claim 67 has been amended to depend from claim 1. The scope of claim 67 is unchanged. The basis for the rejection is believed to have been addressed and overcome. Withdrawal of the rejection is requested.

*(iii) Rejections Under 35 U.S.C. §112, first paragraph (written description).* Claims 1-15, 17, 35, 37-39, 64 and 66-85 have been rejected for alleged failure to comply with the written description requirement. Claim 64 has been cancelled without prejudice or disclaimer. The rejection of claim 64 is thus moot. The rejection is respectfully traversed with respect to the remaining claims.

The written description requirement "ensure[s] that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of

art as detailed in the patent specification.” *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1354 (Fed. Cir. 2000); *Univ. of Rochester v. G. D. Searle & Co.*, 358 F.3d 916, 922 (Fed. Cir. 2004).

Determination of compliance with the written description requirement of section 112 “is a fact-based inquiry that will depend on the nature of the invention.” *Carnegie Mellon Univ. v. Hoffmann-La Roche, Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008), citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002). Written description for a claimed may be provided by disclosure of a “representative number of species” or “by disclosure of relevant, identifying characteristics, i.e., by structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by the combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.” *Id.* at 1125, quoting The Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, “Written Description” Requirement, 66 Fed. Reg. 10-99 (Jan. 5, 2001).

“The ‘written description’ requirement must be applied in the context of the particular invention and the state of the knowledge.” *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). The Federal Circuit has “articulated a variety of factors to evaluate the adequacy of the disclosure supporting ‘generic claims to biological subject matter.’” *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company*, CV 2008-1248, Federal Circuit decision decided April 3, 2009 at page 8, citing *Capon v. Eshhar*, 418 F.3d at 1359. “These factors include the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue.” *Id.*, quoting *Capon v. Eshhar*, 418 F.3d at 1359. “Such knowledge may change as time progresses.” *Carnegie Mellon Univ.*, 541 F.3d at 1122, citing *In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004).

The written description should be withdrawn because the Examiner has failed to state facts that establish a lack of written description. The Examiner first stated basis for lack of written description is that the specification does not disclose a correlation between the structure of the claimed allergens and function. See Office Action at page 7. The Examiner asserts that a large number of features set out in the claims are functional limitations. Office Action at pages 8 through 13, bold type. The Examiner’s assertion is not correct. Features such as spacing between point

mutations, surface exposure of amino acids, sequence identity among proteins, and spacing of mutations such that a circular region of at least  $800 \text{ \AA}^2$  comprises no mutation are not “functional limitations.” These are physical features that describe the amino acids that are mutated in the recombinant mutant allergens and how they are placed. No “function” is explicitly recited or inherently present in these terms. It is thus error for the Examiner to base the present written description rejection, either in whole or in part, on the assertion that there is no correlation of structure to these “functional limitations.”

The Examiner is correct to characterize “reduced IgE binding” as a functional limitation. The specification, however, provides a straight forward disclosure that amino acids to be substituted to reduce IgE binding are preferably located on the surface of an allergen, having a solvent accessibility of at least 20%, and are preferably located in a conserved patch having an area larger than  $400 \text{ \AA}^2$ . This is ample disclosure to show the inventors were in possession of mutations that reduce IgE binding.

The disclosure required to satisfy the written description requirement is measured against the background knowledge in the field. Considering factors for considering genus claims to genetic inventions set out by the Federal Circuit in *Capon* and *Carnegie Mellon*, here, the state of knowledge in the field of allergens was high, both for identifying IgE epitopes and the structural knowledge of the families of allergens recited in the claims, the technology for making allergen mutants and identifying mutations that reduced IgE binding was high, and it was predictable that mutations made according to the guidance set out in the specification would reduce IgE binding. In short, when “applied in the context of the particular invention and the state of the knowledge” (*Capon v. Eshhar*, 418 F.3d at 1357), the specification provides ample disclosure to show the inventors had possession of mutations that “reduced IgE binding.”

For at least the reasons set out above, the written description rejections asserted on the basis of “functional limitations” should be withdrawn.

With regard to the specific rejection of composition claims set out in the Office Action in the middle of page 13, the specification discloses recombinant mutant allergens, explicitly provides that such allergens may be formulated in compositions, and that such compositions may

comprise the precise number of recombinant mutant allergen variants called for in the claims. The specification thus provide explicit support for the composition claims. The Examiner has failed to provide a single fact that supports the conclusion that the specification fails to provide written description for these claims. The written description rejection as it pertains to the composition claims should thus be withdrawn.

For all of the reasons set out above, the claims comply with the written description requirement set out in section 112, first paragraph. Reconsideration of the claims and withdrawal of all written description rejections is requested.

### **III. Conclusion**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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